UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,751	10/19/2001	Lionel Breton	016800-461	6150

7590 11/21/2003

Norman H. Stepno, Esq.
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER	
KIM, VICKIE Y	

ART UNIT	PAPER NUMBER
1614	15

DATE MAILED: 11/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/981,751	BRETON ET AL.	
	Examiner	Art Unit	
	Vickie Kim	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4 and 24-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4 and 24-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

RCE acknowledged

A request for continued examination(RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/17/2003 has been entered.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4 and 24-31 are rejected under 35 U.S.C. 102(b) as being anticipated by over Lee(US 5,132,119, US5,552,162 or US5,569,678).

The instant claims 1 and 4 drawn to a regimen for causing contractile fiber decontraction to relax skin tissue, comprising administering an therapeutically effective amount of at least one inhibitor of at least one calcium channel to a candidate subject in need of such regimen.

Lee's patents(US'119 , US'162 or US'678 hereafter) teach a method for regulating fibroblast biosynthesis via administering calcium channel blockers, see abstract. For instance, US'162 teaches that fibroblast contracts the intact collagen in

order to reduce the surface area of the wound. US'162 also teaches hypertophic scars usually appear at this stage. Thus, one would have envisaged that inhibition of fibroblast biosynthesis would achieved the decontraction/relaxation of the collagen that is conventionally known to be a contractile fiber found in skin tissue by administering a calcium channel inhibitors so that the scarring process can be minimized, prevented or reversed, see US678, column 5, lines 5-10. Even if, Lee's patent is specifically use the term "decontraction/relaxation", it is inherently possessed feature by the regimen taught by the Lee's patents.

Additionally, Lee's patents teach the smoothing the skin tissue via softening, rounding the cell shapes, reducing the scar size and/or fading of the scars, see US'678 at col.11-12.

As to the claims 24-31, Lee's patents teach all the critical elements required by the instant claims, see patented claims in each patent.

For instance, a calcium channel inhibitors required by the instant claims(e.g. a phenylalkylamine, verapamil, calmodulin inhibitos such as trifluperozine) are taught by the cited references, see US'162 claims 2-13. The topical application and subcutaneous or intradermal injection are also taught by the cited references, see US, 119, claims 4-5.

All the critical elements are taught by the cited referenes and thus, all the claims are properly included in this rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee(US 5,132,119, US5,552,162 or US5,569,678) in view of De Lacharriere et al(US 5,869,068).

The teaching of Lee's is mentioned above(supra).

Applicant's claims differ because they require keratolytic agent(e.g. alpha-hydroxy acid or retinoid) as secondary active agent.

However, it would have been obvious to one of ordinary skill in the art to remedy the deficiency of Lee's patents at the time of the invention was made because US'068 teaches the extra benefits obtained by adding keratolytic agent into the regimen for causing contractile fiber decontraction, see abstract.

Although US'068 uses different active agent(chlorine channel inhibitors), one would have been motivated to do , with reasonable expectation of success, because both US'068 and instant invention are drawn to the same regimen and utility(i.e. contractile fiber decontraction and adding extra benefits by secondary active agent such as keratolytic agents to enhance the therapeutic efficacy) that is pertinent to applicant's concern.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Thus, the claimed subject matter is not patentably distinguished over the prior art of the record and all the claims are properly included in this rejection.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 4 and 24-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,344,461 alone, or in alternative, in view of De Lacharriere et al(US 5,869,068).

The claims of US'461 are direct to a regimen for treating wrinkles and/or fine lines using a calcium channel inhibitors. It also teaches all other critical elements required by the instant claims 1, 4 and 24-31, see patented claims 1-11.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the regimen taught by the US '461 patent inherently possesses the feature recited in the instant claims.

Furthermore, the underlying mechanism involving contractile fiber relaxation or contraction utilized in the treatment of wrinkles and fine lines are already known in the art at the time of the invention was made as evidenced by US'068. US'068 teaches wrinkle or fine line treatment that is achieved by administering ion channel blockers such as chlorine channel blocker. As mentioned immediately above, US'068 teaches the underlying mechanism for the said treatment that is associated with contractile fiber decontraction/relaxation. US'068 also teaches the addition of keratolytic agents(retinoid and/or a hydroxy acid) into the patented regimen to enhance the therapeutic efficacy, see abstract. Thus, one would have readily envisaged that the claimed subject matter(i.e. a regiment for causing contractile fiber decontraction/relaxation using a calcium channel inhibitor and optionally, in combination of keratolytic agent to treat wrinkles and fine lines when these references are taken together.

Thus, the claims are properly included in this rejection.

3. It is noted that Young et al(US 5827735) is particularly relevant to the claimed subject matter because US'735 teaches that the fibroblast provides the force for contraction wherein wound contraction is occurred with myofibroblast which is a typical fibroblast and identified in virtually every tissue undergoing active contraction during tissue repair process, see column 3, lines 40 thru column 4, lines 3.

Conclusion

4. No claim is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Primary Patent Examiner
Art unit 1614